

Notice of Allowability

Application No.

10/828,827

Applicant(s)

MOTYKA ET AL.

Examiner

Art Unit

ERNST V. ARNOLD

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/8/10.
2. ☒ The allowed claim(s) is/are 38-40, 43-49 and 52-96 [renumbered as 1-6, 28-34, 13-22, 25, 23, 24, 7-12, 26, 27, 41-53, 35-40, 54 and 55 respectively].

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>7/26/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

/Ernst V Arnold/
Primary Examiner, Art Unit 1616

EXAMINER'S AMENDMENT

This action is responsive to the Board decision of April 07, 2010.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary Oakeson on 7/20/10.

The application has been amended as follows:

In the claims:

In claim 38, line 6, after "composition" insert --- wherein the hypoallergenic metal amino acid chelate composition includes coordinate covalent bonding and has an amino acid to metal ratio from about 1:1 to 3:1. ---

Cancel claims 41 and 42.

In claim 46, line 11, after "subject" insert --- wherein the hypoallergenic metal amino acid chelate composition includes coordinate covalent bonding and has an amino acid to metal ratio from about 1:1 to 3:1. ---

Cancel claims 50 and 51.

In claim 54, line 1, delete "52" and insert --- 53 ---.

Art Unit: 1616

55. (new) A method as in claim 38, wherein the naturally occurring amino acid is selected from the group consisting of alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, and combinations thereof.

56. (new) A method as in claim 38, wherein the metal is selected from the group consisting of iron, zinc, copper, manganese, calcium, chromium, vanadium, selenium, silicon, molybdenum, tin, nickel, boron, cobalt, gold, silver, and combinations thereof.

57. (new) A method as in claim 38, wherein the metal is ferrous iron and the naturally occurring amino acid is glycine, and wherein the glycine to iron molar ratio is about 2:1.

58. (new) A method as in claim 38, wherein the metal is copper and the naturally occurring amino acid is glycine, and wherein the glycine to copper molar ratio is about 2:1.

59. (new) A method as in claim 38, wherein the metal is zinc and the naturally occurring amino acid is glycine, and wherein the glycine to zinc molar ratio is about 2:1.

60. (new) A method as in claim 38, wherein the metal is manganese and the naturally occurring amino acid is glycine, and wherein the glycine to manganese molar ratio is about 2:1.

61. (new) A method as in claim 38, wherein the metal is ferric iron and the naturally occurring amino acid is glycine, and wherein the glycine to ferric iron molar ratio is about 3:1.

Art Unit: 1616

62. (new) A method as in claim 38, wherein the metal is chromium and the naturally occurring amino acid is glycine, and wherein the glycine to chromium molar ratio is about 3:1.

63. (new) A method as in claim 38, wherein the metal is magnesium and the naturally occurring amino acid is glycine, and wherein the magnesium to glycine molar ratio is about 1:1.

64. (new) A method as in claim 38, wherein the metal is calcium and the naturally occurring amino acid is glycine, and wherein the calcium to glycine molar ratio is about 1:1.

65. (new) A method as in claim 38, wherein the hypoallergenic metal amino acid chelate composition is substantially free of allergens such that upon administration of the composition to a subject in an effective amount to cause a medicinal or nutritional result, the composition does not produce a discernable adverse allergic reaction in the subject.

66. (new) A method as in claim 64, wherein the allergens are removed from the naturally occurring amino acid after formation, but before chelation with the metal.

67. (new) A method as in claim 64, wherein the subject is human.

68. (new) A method as in claim 44, wherein the additive is a hypoallergenic organic acid selected from the group consisting of citric acid, fumaric acid, succinic acid, tartaric acid, malic acid, lactic acid, gluconic acid, ascorbic acid, pantothenic acid, folic acid, lipolic acid, oxalic acid, malic acid, formic acid, acetic acid, pyruvic acid, adipic acid, alpha-ketoglutaric acid, and mixtures thereof.

69. (new) A method as in claim 44, wherein the additive is a hypoallergenic filler selected from the group consisting of grain flours, maltodextrins, vegetable flours or powders, inulin, and combinations thereof.

70. (new) A method as in claim 44, wherein the additive is a hypoallergenic flow control agent selected from the group consisting of fumed silica, stearic acid, talc, and combinations thereof.

71. (new) A method as in claim 44, wherein the additive is selected from the group consisting of hypoallergenic free amino acids, hypoallergenic amino acid salts, and combinations thereof.

72. (new) A method as in claim 44, wherein the additive is selected from the group consisting of vitamins, coenzymes, cofactors, herbs, herbal extracts, protein powders, and combinations thereof.

73. (new) A method as in claim 44, wherein the additive is selected from the group consisting of mineral oils, binders, flavoring or taste-free additives, and combinations thereof.

74. (new) A method as in claim 38, wherein the amino acid source is prepared by synthetic synthesis.

75. (new) A method as in claim 38, wherein the amino acid source is prepared by fermentation.

76. (new) A method as in claim 46, wherein the naturally occurring amino acid is selected from the group consisting of alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, and combinations thereof.

Art Unit: 1616

77. (new) A method as in claim 46, wherein the metal is selected from the group consisting of iron, zinc, copper, manganese, calcium, chromium, vanadium, selenium, silicon, molybdenum, tin, nickel, boron, cobalt, gold, silver, and combinations thereof.

78. (new) A method as in claim 46, wherein the metal is ferrous iron and the naturally occurring amino acid is glycine, and wherein the glycine to iron molar ratio is about 2:1.

79. (new) A method as in claim 46, wherein the metal is copper and the naturally occurring amino acid is glycine, and wherein the glycine to copper molar ratio is about 2:1.

80. (new) A method as in claim 46, wherein the metal is zinc and the naturally occurring amino acid is glycine, and wherein the glycine to zinc molar ratio is about 2:1.

81. (new) A method as in claim 46, wherein the metal is manganese and the naturally occurring amino acid is glycine, and wherein the glycine to manganese molar ratio is about 2:1.

82. (new) A method as in claim 46, wherein the metal is ferric iron and the naturally occurring amino acid is glycine, and wherein the glycine to ferric iron molar ratio is about 3:1.

83. (new) A method as in claim 46, wherein the metal is chromium and the naturally occurring amino acid is glycine, and wherein the glycine to chromium molar ratio is about 3:1.

84. (new) A method as in claim 46, wherein the metal is magnesium and the naturally occurring amino acid is glycine, and wherein the magnesium to glycine molar ratio is about 1:1.

Art Unit: 1616

85. (new) A method as in claim 46, wherein the metal is calcium and the naturally occurring amino acid is glycine, and wherein the calcium to glycine molar ratio is about 1:1.

86. (new) A method as in claim 46, wherein the hypoallergenic metal amino acid chelate composition is substantially free of allergens such that upon administration of the composition to the subject in an effective amount to cause a medicinal or nutritional result, the composition does not produce a discernable adverse allergic reaction in the subject.

87. (new) A method as in claim 86, wherein the allergens are removed from the naturally occurring amino acid after formation, but before chelation with the metal.

88. (new) A method as in claim 46, wherein the subject is human.

89. (new) A method as in claim 53, wherein the additive is an hypoallergenic organic acid selected from the group consisting of citric acid, fumaric acid, succinic acid, tartaric acid, malic acid, lactic acid, gluconic acid, ascorbic acid, pantothenic acid, folic acid, lipoic acid, oxalic acid, maleic acid, formic acid, acetic acid, pyruvic acid, adipic acid, alpha-ketoglutaric acid, and mixtures thereof.

90. (new) A method as in claim 53, wherein the additive is a hypoallergenic filler selected from the group consisting of grain flours, maltodextrins, vegetable flours or powders, inulin, and combinations thereof.

91. (new) A method as in claim 53, wherein the additive is a hypoallergenic flow control agent selected from the group consisting of fumed silica, stearic acid, talc, and combinations thereof.

92. (new) A method as in claim 53, wherein the additive is selected from the group consisting of hypoallergenic free amino acids, hypoallergenic amino acid salts, and combinations thereof.

93. (new) A method as in claim 53, wherein the additive is selected from the group consisting of vitamins, coenzymes, cofactors, herbs, herbal extracts, protein powders, and combinations thereof.

94. (new) A method as in claim 53, wherein the additive is selected from the group consisting of mineral oils, binders, flavoring or taste-free additives, and combinations thereof.

95. (new) A method as in claim 46, wherein the amino acid source is prepared by synthetic synthesis.

96. (new) A method as in claim 46, wherein the amino acid source is prepared by fermentation.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: **See Board of Patent Appeals and Interferences decision rendered on 4/7/10.**

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1616

Conclusion

Claims 38-40, 43-49 and 52-96 [renumbered as 1-6, 28-34, 13-22, 25, 23, 24, 7-12, 26, 27, 41-53, 35-40, 54 and 55 respectively].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1616